the requirements in the section titled "Eligible Applicants" will not be included in the review process.

As stated, CCF monies must be used towards the organization's capacity-building and not for direct services. Additionally, organizations that receive CCF funds may not engage in inherently religious activities, such as worship, religious instruction, or proselytization, as part of the programs or services funded with CCF funds. If an organization conducts such inherently religious activities, the activities must be offered separately, in time or location, from the programs or services funded with CCF assistance, and participation must be voluntary for beneficiaries of the CCF-funded programs or services. In addition, an organization receiving CCF funds shall not, in providing CCF-funded services, discriminate against a program beneficiary or prospective program beneficiary on the basis of religion or religious belief.

Approved But Unfunded Applications

Applications that are approved but unfunded may be held over for funding in the next funding cycle, pending the availability of funds, for a period not to exceed one year.

VI. Award Administration Information

1. Award Notices

The successful applicants will be notified through the issuance of a Financial Assistance Award document which sets forth the amount of funds granted, the terms and conditions of the grant, the effective date of the grant, the budget period for which initial support will be given, the non-Federal share to be provided, and the total project period for which support is contemplated. The Financial Assistance Award will be signed by the Grants Officer and transmitted via postal mail.

Organizations whose applications will not be funded will be notified in writing.

2. Administrative and National Policy Requirements

Direct Federal grants, sub-award funds, or contracts under this Compassion Capital Fund Intermediary Demonstration Program shall not be used to support inherently religious activities such as religious instruction, worship, or proselytization. Therefore, organizations must take steps to separate, in time or location, their inherently religious activities from the services funded under this Program. Regulations pertaining to the Equal Treatment For Faith-Based Organizations, which includes the prohibition against Federal funding of inherently religious activities, can be found at either 45 CFR 87.1 or the HHS Web site at *http://www.os.dhhs.gov/fbci/waisgate21.pdf.*

45 CFR Part 74

45 CFR Part 92

Grantees are subject to the requirements in 45 CFR part 74 (non-governmental) or 45 CFR part 92 (governmental) as well as 45 CFR part 87.

3. Reporting Requirements

Programmatic Reports: Semi-Annually.

Financial Reports: Semi-Annually.

Grantees will be required to submit program progress and financial reports (SF 269) throughout the project period. Program progress and financial reports are due 30 days after the reporting period. In addition, final programmatic and financial reports are due 90 days after the close of the project period.

Original reports and one copy should be mailed to:

Administration for Children and Families, Office of Grants Management, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., Washington, DC 20447.

Grantees may be asked to participate in a national evaluation of the Compassion Capital Fund program. The program will cooperate with any research or evaluation efforts sponsored by the Administration for Children and Families (ACF).

VII. Agency Contacts

Program Office Contact

Kelly Cowles, Office of Community Services, 370 L'Enfant Promenade, SW., Suite 500 West, Aerospace Building, Washington, DC 20447–0002. Phone: (800) 281–9519. E-mail: *ocs@lcgnet.com.*

Grants Management Office Contact

Barbara Ziegler-Johnson, Office of Grants Management, Division of Discretionary Grants, 370 L'Enfant Promenade, SW., 4th Floor West, Aerospace Building, Washington, DC 20447–0002. Phone: (800) 281–9519. E-mail: *ocs@lcgnet.com.*

VIII. Other Information

Notice: Beginning with FY 2006, the Administration for Children and Families (ACF) will no longer publish grant announcements in the **Federal Register**. Beginning October 1, 2005 applicants will be able to find a synopsis of all ACF grant opportunities and apply electronically for opportunities via: *http://www.Grants.gov.* Applicants will also be able to find the complete text of all ACF grant announcements on the ACF Web site located at: *http://www.acf.hhs.gov/grants/index.html.*

Additional information about this program and its purpose can be located on the following Web sites: *http://www.acf.hhs.gov/programs/ccf/.*

Applicants will be sent acknowledgements of received applications.

Dated: April 25, 2005.

Josephine B. Robinson,

Director, Office of Community Services.

[FR Doc. 05–8608 Filed 4–28–05; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003E–0259]

Determination of Regulatory Review Period for Purposes of Patent Extension; GEODON

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for GEODON and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Claudia Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6699.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive,

or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product GEODON (ziprasidone hydrochloride). GEODON is indicated for the treatment of schizophrenia. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for GEODON (U.S. Patent No. 4,831,031) from Pfizer, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 16, 2003, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of GEODON represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for GEODON is 3,933 days. Of this time, 2,511 days occurred during the testing phase of the regulatory review period, while 1,422 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i) became effective*: May 3, 1990. FDA has verified the applicant's claim that the date the Investigational New Drug application became effective was on May 3, 1990.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act*: March 17, 1997. FDA has verified the applicant's claim that the new drug application (NDA) for GEODON (NDA 20–825) was initially submitted on March 17, 1997.

3. *The date the application was approved*: February 5, 2001. FDA has verified the applicant's claim that NDA 20–825 was approved on February 5, 2001.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,825 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by June 28, 2005. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 26, 2005. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 5, 2005.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 05–8587 Filed 4–28–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Native American Research Centers for Health (NARCH) Grants

Announcement Type: New.

Funding Opportunity Announcement: HHS–2005–IHS–NARCH–0001.

Catalog of Federal Domestic Assistance Numbers (s): 93.933.

Key Dates: Release Date: May 2005. Letter of Intent Deadline: August 1, 2005. Application Deadline Date: September 14, 2005. Review Date: November 2005. Earliest Anticipated Start Date: June 1, 2006.

Due Dates for E.O. 12372: Not Applicable.

Summary

The Indian Health Service (IHS), with the National Institute of General Medical Sciences (NIGMS) of the National Institutes of Health announces an initiative to support the Native American Research Centers for Health (NARCH) grant. This funding mechanism will develop opportunities for conducting research and research training to meet the needs of American Indian/Alaska Native (AI/AN) communities. The estimated funds (total costs) available for the first year of support for the entire initiative is expected to be over $2.2 million in FY 2006. The actual amount may vary, depending on the response to the Request for Applications (RFA) and the availability of funds. Eligibles include federally-recognized Indian Tribes, Tribally sanctioned non-profit Tribal organizations, Non-profit national or area Indian health boards, and consortiums of two or more of those Tribes, Tribal organizations, or health boards.

I. Funding Opportunity Description

Purpose of the RFA

The NARCH initiative will support partnerships between AI/AN Tribes or Tribally-based organizations such as the National Indian Health Board and Area Health Boards, and institutions that conduct intensive academic-level biomedical, behavioral and health services research. These partnerships are called Native American Research Centers for Health (NARCH). The purposes of the NARCH initiative are:

1. To develop a cadre of AI/AN scientists and health professionals engaged in biomedical, clinical, behavioral and health services research who will be competitive in securing